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STATE FOR EAP/ANP, EB, STATE PASS TO USTR BWEISEL, GBLUE
AND DBELL, COMMERCE FOR ITA/MAC/AP/OSAO, TREASURY FO OASIA

E.O. 12958: N/A
TAGS: ECON EFIN ETRD NZ
SUBJECT: NEW ZEALAND - 2008 NATIONAL TRADE ESTIMATE REPORT

REF: STATE 119765

¶1. Following is Post's submission for the 2008 National Trade Estimate Report (NTE) regarding New Zealand per request reftel. We assume that Washington agencies will provide updated trade and investment data.

¶2. Begin text of NTE submission:

IMPORT POLICIES

In general, tariff rates in New Zealand are low as a result of several rounds of unilateral tariff cuts that began in the mid-1980s and continued until the current Labour government, elected in 1999, froze further reductions until July 2005. The New Zealand government announced in September 2003 that it would resume unilateral tariff reductions starting July 1, ¶2006. Under this unilateral tariff reduction program, New Zealand has begun implementing gradual reductions of its highest tariff rates (currently 17 percent), which will reduce tariffs to 10 percent by July 1, 2009. These top rates apply mostly to clothing, footwear and carpet. Ad valorem tariffs on all other dutiable goods will be reduced to 5 percent by July 1, 2008.

STANDARDS, TESTING, LABELING AND CERTIFICATION

Biotechnology Regulations

New Zealand's Environmental Risk Management Authority (ERMA), an independent body, reviews applications for the release of new organisms, including biotechnology products that contain living organisms. ERMA assesses applications on a case-by-case basis and can issue four types of approvals: initial development in containment (such as in a laboratory or glass house outdoor development or field test (in containment), conditional release, and full, unconditional release (with no controls). Biosecurity New Zealand, part of the Ministry of Agriculture and Forestry (MAF), carries out compliance and enforcement of all indoor and outdoor containment and conditional release approvals. When assessing a containment application, ERMA focuses on the adequacy of containment to mitigate any potential effect of the organism on the environment.

Since 1998, ERMA has granted approximately fifteen approvals for contained field trials of genetically modified crops. Of these, approximately five have been completed, six are still ongoing, and the remaining approvals have either ceased or were unused for various reasons. To date, there have been no

applications for either a conditional or a full release of products derived by the use of biotechnology in New Zealand. The most recent approval granted by ERMA was in May 2007 for Crop and Food Research to conduct a contained field test for broccoli, cabbage, cauliflower and forage kale derived by the use of biotechnology and engineered for pest resistance. Three years ago, ERMA approved an application from the same organization to field test onions derived by the use of biotechnology.

Release approvals include both conditional release, where controls can be placed on the organism to manage risks, and full release where no controls are imposed. The process for outdoor containment, conditional and full release of biotechnology products is much more onerous than for an indoor containment application. Among other things, applicants must provide ERMA with detailed information and analysis that enables them to conduct a full-scale risk assessment that takes into account a broad range of scientific, economic, cultural and ethical factors in the decision making process. This includes the possible impact of a release on New Zealand's clean, green image and the potential impact on the Maori culture. All outdoor containment, conditional and full release applications must be publicly notified. In addition, a Maori consultation is required.

Until October 2003, New Zealand maintained a voluntary two-year moratorium on the introduction of all biotechnology products, which precluded applications for the commercial planting of biotechnology crops, the commercial importation of seeds derived by the use of biotechnology, the release into the environment of animals derived by the use of

biotechnology and, to a lesser extent, some human and veterinary medicines containing biotechnology products. The moratorium, however, did not apply to the use and sale of processed foods and ingredients derived by the use of biotechnology. With the moratorium's expiration and the report of the Royal Commission on Genetic Modification, Parliament amended the Hazardous Substances and New Organisms Act 1996 to make the regulation of biotechnological research more workable and to facilitate controlled release of biotechnology products. The amendment, the New Organisms and Other Matters Bill of 2003, introduced the conditional release category for approval of new organisms.

Biotechnology Food Approval

Foods with genetically modified content can be offered for sale and consumption in New Zealand after being assessed and approved by Food Standards Australia New Zealand (FSANZ), which is the bi-national food regulatory authority for New Zealand and Australia. FSANZ is responsible for the development of regulations in the Australia - New Zealand Food Standards Code (Code). The New Zealand Food Safety Authority (NZFSA) is responsible for implementation and enforcement within New Zealand.

A mandatory standard for foods produced using modern biotechnology came into effect in mid-1999. The standard, which was established under the Food Act of 1981, prohibits the sale of food produced using genetic modification unless such food has been assessed by FSANZ and listed in the food code standard. As of November 2007, FSANZ has received a total of 39 applications for assessment of genetically modified foods. Of these, thirty-three applications have been approved and four are under assessment. Two requests have been withdrawn.

Biotechnology Food Labeling

Mandatory labeling requirements for genetically modified foods took effect in December 2001. With few exceptions, a food in its final form that contains detectable DNA or

protein derived from genetic modification must be so labeled. Meeting New Zealand's food labeling regulations for genetically modified foods can be extremely burdensome and is especially relevant for U.S. agricultural exporters who deal primarily in processed food. New Zealand wholesalers and retailers frequently demand GM-free declarations from their suppliers. This effectively places liability for any GM labeling non-compliance on the importer. New Zealand food legislation requires businesses to exercise due diligence in complying with food standards, which usually is defined as maintaining a paper or audit trail similar to a quality assurance system.

The NZFSA conducts periodic compliance audits. Violators of food labeling requirements can be assessed penalties under the Food Act 1981. As part of the Domestic Food Review, the New Zealand Government is reviewing the entire Food Act and a new version is expected to be introduced to parliament in the first quarter of 2008.

Sanitary and Phytosanitary Measures

New Zealand maintains a strict regimen of sanitary and phytosanitary (SPS) controls for virtually all imported agricultural products. The United States and New Zealand continue to discuss specific SPS issues that negatively impact trade in products supplied by the United States as part of our annual Trade and Investment Framework Agreement (TIFA) dialogue and in other fora.

In 2006, New Zealand implemented new processes for undertaking risk analyses and developing import health standards. This initiative is intended to streamline existing processes and provide consistency in the way New Zealand undertakes these tasks. As of July 1, 2006, New Zealand also implemented a new system for funding and managing the development of import health standards. The new system is intended to be more transparent, direct government resources to the highest priorities and increase the resources available for developing import health standards.

During the 2006 U.S.- New Zealand TIFA discussions, the

United States Government requested that New Zealand develop an import standard for Pacific Northwest stone fruit (plums, peaches, nectarines and apricots). In response to the US. request, New Zealand has added Pacific Northwest stone fruit to its import health standard development work program. The work program also includes a review of import requirements for citrus from the United States.

New Zealand completed a risk assessment of U.S. high-value pork in June of 2006. To date, this product has been subject to a pre-cooking requirement because of the presence of Porcine Reproductive and Respiratory Syndrome (PRRS) in the United States. While the analysis confirmed that there is a risk of PRRS disease entering New Zealand, the Ministry of Agriculture and Forestry (MAF) is recommending that high value cuts of pork be allowed entry without any sanitary treatment. In response to the risk assessment, MAF received forty-four submissions, including two from the United States. MAF completed the review of submissions in June 2007 and is expected to announce the draft import health standard by the end of the calendar year.

The New Zealand Food Safety Authority (NZFSA) requires case-by-case assessment of U.S. bovine products before importation due to concerns over Bovine Spongiform Encephalopathy (BSE). In February 2007, NZFSA announced a move to modernize its food safety importing requirements for beef and beef products in light of the new science that surrounds BSE. Among other things, the new measures will enable New Zealand to categorize the BSE risk status of countries exporting to New Zealand. Once these measures are finalized, the current requirement to assess U.S. products on

a case-by-case basis is expected to be eliminated.

New Zealand continues to suspend imports of U.S. poultry meat (except canned product) due to its restrictions on countries that have infectious bursal disease.

(Note: New Zealand makes a functional distinction between the use of the terms biotechnology and genetic modification. End note).

INTELLECTUAL PROPERTY RIGHTS PROTECTION (IPR)

Copyright Protection

The New Zealand government introduced the Copyright Amendments Bill at the end of 2006, which passed its first reading. In 2007, the legislation was sent to Select Committee for a comment period. The Bill was again taken up by Parliament in November 2007 for a second reading but it is uncertain whether the Bill in its current form has sufficient votes to pass. If the current Bill form does not pass the second reading before the end of this year's legislative term, then it is unlikely to be dealt with again until after the election period, i.e., 2009. In March 2007, during the comment period to the Select Committee, industry argued that the draft legislation would put New Zealand at odds with the growing international consensus with respect to protection of copyright in the on-line environment. The international standards for protection of copyrightable material are currently set by the WIPO Internet Treaties (the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty) of which New Zealand is not a signatory. Industry's main concerns regarding the draft legislation relate primarily to the following:

The Bill fails to adequately protect Technological Protection Measures (TPMs) that prevent unauthorized access to digital content. The viability of many existing and prospective business models depend on such TPMs, but the Bill excludes protection for the very types of access controls most in need of it. In order to meet the minimum level of protection required by the WIPO treaties, both access and copy protection TPMs must be protected, separate and apart from the remedies available for infringement. There is inadequate protection against the sale of circumvention (hacking) devices. In its present form, the Bill would allow the sale of circumvention devices as long as the device is capable of any "significant application" other than circumvention. Thus the provider of a circumvention device could avoid liability so long as the tool performs some other function. Moreover, the Bill only prohibits trafficking in circumvention devices

where the trafficker has knowledge or reason to believe that the device will, or is likely to be, used for infringement. This allows any trafficker to hypothesize a non-infringing use for the tools of his trade as a defense. In this way, a proliferation of such devices would be encouraged, thus eviscerating any protections for TPMs.

Internet Service Providers (ISPs) are provided a "safe harbor" from liability without requiring them to apply a repeat-infringer termination policy. The Bill also allows ISPs to escape liability even if they have "reason to know" that infringing activity is taking place on their networks, yet fail to act. The only requirement is that they have "actual knowledge or awareness" of infringement - which constitutes a high burden of proof for right holders, and would encourage unlawful activity. Also of significant concern, is the addition of a provision that would make it an offense to provide inaccurate information to ISPs regarding illegal content on their networks. This provision further adds to the burdens of content owners, who already take care and incur significant expense to monitor the use of their content on third party networks.

Patent Protection

In 2000, the Government initiated a review of the Patents Act of 1953. Although an initial draft Bill was released in early 2005 for consultation, it has yet to have its first reading in the legislature. The stated purpose of the Bill is to ensure that New Zealand's patent regime takes account of international developments. One such development is the international trend for countries to strengthen intellectual property protection through patent term restoration. On average, the patent and regulatory approval processes for new drugs in New Zealand take about twelve years. As a result, many drugs have very few years of patent protection remaining after the regulatory authority grants marketing approval. Many countries, including the U.S. and EU, have established mechanisms to restore patent terms for pharmaceutical products to recover time lost due to regulatory delays. The research-based industry has urged the New Zealand legislature to amend the current bill to include patent term restoration in keeping with international best practices.

The issue of the patent term protection for pharmaceuticals was the subject of a consultation exercise by the Ministry of Economic Development in 2003. After considering all submissions and available information, the Ministry decided that it was not possible to determine whether the benefits of extending the patent term for pharmaceuticals would exceed the likely costs, and proposed that an economic study be carried out to gather more information on the subject. After considering the terms of reference for such a study, the government decided in 2004 that no further work needed to be done on this issue.

Changes to IPR Enforcement

In the copyright legislation currently under Parliamentary consideration, there are provisions to strengthen enforcement of trafficking in counterfeit goods and pirated works by empowering the Ministry of Economic Development to be able to investigate and prosecute the criminal offenses for manufacturing, importing and selling of counterfeited goods and pirated works. The Government is also reviewing New Zealand Customs' border powers to prevent importation of counterfeit goods and pirated works. Additionally, the New Zealand has agreed to join negotiations on the Anti-Counterfeiting Trade Agreement (ACTA), proposed by the U.S. and Japan.

SERVICES BARRIERS

Local Content Quotas

Radio and television broadcasters have adopted voluntary local content targets, but only after the New Zealand government made it clear that it would otherwise pursue mandatory quotas. Although New Zealand government officials have said they are sensitive to the implications of quotas under the WTO General Agreement on Trade in Services (GATS), they reserve the right to impose them.

Telecommunications

In September 2007, the New Zealand government announced that it was going ahead with its plan to split Telecom New Zealand into three separate operational units to provide retail, wholesale and network services. The determination sets requirements for Access Network Services (ANS) to provide services over existing copper, and future fiber and wireless access networks, ensuring comprehensive service coverage and ensuring that the unit is forward-looking.

Telecommunications Regulatory Environment

In November 2005, the Government commenced an assessment of

the telecommunications sector. The purpose of the assessment was to consider developments of the telecommunications sector as a whole over the medium term (three to five years). The stock take found that the local loop (subscriber line, i.e., customer to carrier connection) remains an access bottleneck that restricts the development of effective competition. New entrants require access on fair and non-discriminatory terms to Telecom's network to be able to provide high quality, cost effective and differentiated services.

"Last-mile" access for the majority of New Zealand consumers is likely to rely heavily on the local copper network for sometime. The stock take analysis also indicated that an improved Unbundled Bitstream Service (UBS) would help close the gap with other OECD countries on broadband uptake, price and quality.

The assessment resulted in the Telecommunications Amendment Act 2006. The Act was passed through Parliament in December ¶2006. The main parts of the Act are requiring the operational separation of Telecom; extending the range of services subject to regulation; enhancing the ability of the Commissioner to implement regulated services; and empowering the Commissioner to monitor compliance in the sector.

The key features of the Act are:

-- Operational separation of Telecom New Zealand in order to promote competition in the telecommunications market (see below).

-- Regulating for greater access to Telecom's local loop by competitors by introducing new regulated Unbundled Local Loop ULL and Unbundled Bit stream Access (UBA), naked DSL services and unbundled backhaul services.

-- Improving transparency of Telecom's costs and pricing via regulating for the accounting separation of Telecom.

-- Enhancing the Telecommunications Commissioner's ability to implement services by ensuring that service providers can get effective and timely access to regulated services.

-- Standard terms determination introduced allowing the Commerce Commission to set terms of supply for regulated services by providing a multilateral process for setting these terms. This will allow the Commerce Commission to resolve supply terms for regulated services once, rather than for each access seeker individually.

-- Giving the Telecommunications Commissioner the ability to initiate multi-network determinations where the Commissioner will be empowered to initiate a determination of the terms and conditions of regulated multi-network services, rather than relying on access seekers to apply.

The Act requires:

-- The separation of Telecom into separate Access Network Services, Wholesale and Retail business units;

-- A requirement for Access Network Services to be operated on a stand-alone basis and for Telecom Wholesale to be operated at arms-length from any retail business units;

-- The establishment of an Independent Oversight Group, backed up by Commerce Commission enforcement, to ensure Telecom faithfully implements its Separation plan; and

-- A requirement that relevant products, especially Local Loop Unbundling and Unbundled Bit stream Access, are available to all market participants on equivalent terms.

-- As part of the operational separation process, the

Minister of Communications issued a Determination on 26 September 2007 of further requirements with which Telecom's undertakings must comply. Telecom has 20 working days from the Determination date to prepare their draft separation plan.

Mobile Termination Rates

At the end of April 2007, the Economic Development Minister announced that he would accept voluntary, and separate binding deeds from Vodafone and Telecom New Zealand. The deeds provide for each company's performance in passing through reductions in mobile termination rates to fixed calling customers to be independently audited each year. Each deed also contains measures to ensure the independence of the verification process.

Under the deeds, Telecom will reduce its mobile termination rate from 20 cents per minute (cpm) to 12 cpm and Vodafone has offered to reduce its mobile termination rate from 20 cpm to 14 cpm, both over the next five years. These are in line with the Commerce Commission's estimate that the cost of mobile termination in New Zealand would be 15 cpm trending down to 12 cpm in five years time.

INVESTMENT BARRIERS

Investment Screening

New Zealand's Overseas Investment Office (0I0) screens foreign investments in: business investments that exceed NZ$100 million and represent 25% equity or more and; investments in land defined as sensitive within the Overseas Investment Act 2005 (the Act); and investment in Fishing Quota. The New Zealand government enacted The Overseas Investment Act in August 2005, which liberalized the investment screening regime by refocusing screening on assets of critical interest. The review also strengthened the monitoring and enforcement of conditions of consent made under the Act.

The screening threshold for investments of over 25%, or a control interest in, non-land business investments was raised from NZ$50 million to NZ$l00 million. Investors are required to satisfy the "investor test" that requires investors be of good character, are not excluded from entering New Zealand under the Immigration Act and be able to display both financial commitment and business acumen. Significantly, no business investments have been declined since 1984.

The purchase of land defined as sensitive within the Act requires approval. Examples of sensitive land could include: non-urban land of over five hectares, land on certain offshore islands, or land that includes or adjoins foreshore and seabed. Most urban land is not screened at all unless deemed to be sensitive for other reasons. Investments by overseas persons who are not intending to reside in New Zealand are required to pass the "investor test" and show that the investment will create a benefit for New Zealand. In considering whether this benefit exists, consideration is required to be given to a range of economic and non-economic factors included within the Act. Where the investor has undertaken to generate these benefits (e.g. through significant development or investment) the realization of these benefits may be included as conditions of consent and progress may be periodically monitored.

The United States has raised concerns about the continued use of this screening mechanism. New Zealand's maintain that its commitments under the WTO General Agreement on Trade in Services are reflected in the OIO screening program.

OTHER BARRIERS

Government Price Controls and Reimbursement for Pharmaceuticals

The U.S. Government continued to raise concerns about New

Zealand's support for innovation in the research and development of innovative pharmaceutical products. New Zealand's Pharmaceutical Management Agency (PHARMAC), a stand-alone Crown entity, administers a Pharmaceutical Schedule that lists medicines subsidized by the New Zealand government. The schedule also specifies conditions for prescribing a product listed for reimbursement. PHARMAC accounts for 73 percent of New Zealand's expenditures on prescription drugs. The New Zealand government also supports hospitals' pharmaceutical expenditures, bringing its share of total spending on prescription drugs in the country to about 80 percent.

With respect to accountability, PHARMAC (as a Crown Entity) is accountable to the Minister of Health and has a Board of Directors appointed by the Minister. PHARMAC also operates in practice as an agent of the District Health Boards (DHBs) and its capped (notional) pharmaceutical budget is funded by the DHBs.

PHARMAC reports both monthly and quarterly to the Ministry of Health (acting on behalf of the Minister of Health). In addition, the Minister of Health may at any time ask the PHARMAC Board for a "please explain," and has the power to dismiss Board Members. PHARMAC staff members are accountable to its Board of Directors who scrutinize not just the substance of their actions, but also ensure a rigorous adherence to the Operating Policies and Procedures (OPPs).

New Zealand does not restrict the sale of non-subsidized pharmaceuticals in the country. However, private medical insurance companies will not cover the cost of non-subsidized medicines and doctors are often reluctant to prescribe them to patients who would have to pay the cost themselves. Thus, PHARMAC's decisions have a major impact on the availability and price of non-subsidized medicines and the ability of pharmaceutical companies to sell their products in the New Zealand market.

PHARMAC continues to operate stringent cost containment strategies, and issues of transparency, predictability and accountability remain unresolved in industry's opinion. New Zealand has created a commercially difficult market for innovative medicines. In October 2005, the United Future Party announced that it had secured an agreement from the Labour Party to develop a national medicines policy as part of Labour's coalition negotiations to form a Government. This is tantamount to a review of the Government's pharmaceutical policy, and includes three areas of focus: Access to Medicines; Quality Use of Medicines; and the Rational Use of Medicines. The national medicines policy will be released through the Ministry of Health and is anticipated to be released as a consultation document in December 2007 with some principles and possible solutions proffered. There will follow a consultation period from the time of release, with changes expected to be implemented later in 2008.

Market Access for Pharmaceuticals

The innovative pharmaceutical industry is advocating for the following key policy reforms in New Zealand:

-- Patient Outcomes - The National Medicines Strategy (NMS) should ensure the provision of quality medicines in a way that is responsive to people's needs and achieves optimal health outcomes.

-- Comparable Access - The NMS should ensure that New Zealanders have at least comparable access to medicines as do citizens in other OECD countries.

-- A Core Health Strategy - Medicines play a vital role in the prevention, amelioration and treatment of disease and as such the NMS is integral to the achievement of all national

health strategies and should have equal standing and priority.

-- Integrity and Public Confidence - The current bundling of clinical assessment and procurement decisions creates incentives to subordinate clinical judgment to budget imperative. For these decisions to have integrity and improve public confidence in the system, determinations about which medicines are cost effective and are of clinical merit

must be conducted independently before being used to form decisions about which products can be funded.

-- Transparency and Rigor of Processes and Decision Making - Public confidence will be enhanced if decision making processes are underpinned by openness, fairness, timeliness and high standards of consultation and review. All stakeholders must be able to understand the true basis of decisions and rationing should be explicit. What is considered 'value for money' should comparable to other OECD countries and meet WHO recommendations. Health Technology Assessment (HTA) methodologies must be rigorous and up to world standards.

-- Recognition of the Value of Innovation - The NMS should recognize the value of innovation and innovative pharmaceuticals through the adoption of procedures that appropriately value the objectively demonstrated therapeutic significance of the pharmaceutical.

-- Responsive Budget Management - The pharmaceutical budget should be determined by need and access benchmarks. Rather than conduct health technology assessments (HTA) of products after the capped budget has been set, thus simply creating a priority list of new products competing for the limited funding available, horizon scanning and HTA should be used to establish budget estimates on an annual basis.

-- Partnership - The achievement of timely access to medicines, quality use of medicines and other NMS objectives is greatly enhanced by the maintenance of a responsible and viable industry in New Zealand. Coordination of health and industry policies and a consistent and more welcoming environment will better enable the industry to effectively partner the government and other stakeholders to achieve improved health and economic outcomes.

-- Whole of System - The NMS must be a whole of system approach. Meaningful and sustainable improvements will only be achieved by a comprehensive, system wide, review. Selecting and pursing only a limited range of issues will not meet public expectations for reform and would negatively impact the relevance and effectiveness of the National Medicines Strategy.

Therapeutic Products and Medicines Bill

The New Zealand and Australian governments signed a treaty on December 10, 2003, with the intent to create a joint agency to regulate medical devices, prescription and over-the-counter medicines, dietary and nutritional supplements, and cosmetics such as sun creams. Aside from prescription pharmaceuticals, New Zealand does not currently regulate market entry of these products, but would have done so under proposed regulations. Implementing legislation known as the Therapeutic Products and Medicines Bill was introduced at the end of 2006 and barely passed its first reading. After a prolonged political battle, on July 16, 2007, the State Services Minister put the highly contentious Bill "on hold." The New Zealand Government has shelved the legislation, ending any near term prospects of a joint New Zealand - Australia agency to regulate prescription and over-the-counter medicines and medical devices. After lengthy contentious political debate, the Government could not secure enough votes in Parliament to ensure the bill's

passage into law. This almost certainly means the Bill's prospects of passage are dead until after the 2008 election.

The bill was expected to grandfather products that were already lawfully on the market at the time of the implementation of the legislation. The Bill would have granted an interim license valid for a transition period of three years. It was expected that the new agency would have charged full cost-recovery fees to register products and require additional documentation and assessments for certain products, even if they already have U.S. Food and Drug Administration approval.

GOVERNMENT PROCUREMENT

New Zealand is not a signatory to the WTO Government Procurement Agreement and is not an observer to the Committee on Government Procurement. It is important to note that New

Zealand has a unilateral open market procurement policy, and does not use government procurement measures as trade barriers. The position regarding participation in the Government Procurement Agreement is kept under review. END TEXT.

McCormick